

Introduction

At NOTICE, we are committed to ensuring that all our operations and interactions uphold impartiality, confidentiality and independence core principles. Our stringent policies and procedures are designed to provide unbiased and ethical conformity assessments, safeguarding the integrity of the certification process. By maintaining a clear separation of roles, implementing effective conflict of interest measures, and ensuring the utmost confidentiality of client information, we strive to foster trust and confidence in the quality and safety of medical devices worldwide.

NOTICE Impartiality, Confidentiality & Independency Declaration

Impartiality 

- Equal Treatment
- Conflict of Interests Policies
- Unbiased Decision-making

Independency 

- Unbiased Decision-making
- Separation of Roles
- Prohibition of Certain Relationship

Confidentiality 

- Data Protection
- Controlled Disclosure
- Personal responsibility

IMPARTIALITY, CONFIDENTIALITY & INDEPENDENCY DECLARATION

NOTICE declares their commitment to maintaining impartiality, confidentiality, and independence in all aspects of operations and interactions. It recognizes the importance of unbiased decision-making and ethical conduct in achieving our mission and upholding our core values.

NOTICE is committed to treating all companies equally and impartially regardless of their geographic location, size, or association with any organizations. All NOTICE employees and committee members, who participate in the conformity assessments are also committed to adhere to impartiality and confidentiality principles and they will provide services based on objective evidence of conformity without favouring any organization or individuals.

NOTICE is committed to implementing effective conflict of interest policies and procedures to identify, prevent, and appropriately manage conflicts that could compromise impartiality. For this purpose, NOTICE has thoroughly assessed and examined the risks linked to conflicts of interest and has taken all essential precautions and maintains a continuous review of the risk analysis to ensure ongoing effectiveness.

NOTICE has established procedures to ensure that personnel (internal, external, and subcontractors) involved in conformity assessment processes in accordance with accreditation standards and related EU regulations are distinct from personnel involved in post-audit decision-making processes.

NOTICE's top management commits to not influencing decision-making processes related to conformity assessments in a positive or negative way, to suspend the relevant process(s) if a situation impairing their impartiality is detected, and to avoid any behavior that might jeopardize the client's organizations' reputation.

NOTICE top management provides all necessary resources to ensure a competent, open, impartial and independent product conformity assessment and quality management system assessment process.

NOTICE top management ensures the provision of all essential resources to facilitate a competent, transparent, impartial, and independent process for product conformity assessment and quality management system assessments.

NOTICE commits to complying with all applicable laws, regulations, and standards and will stay updated on legal requirements and proactively integrate them into their operations to ensure impartiality and ethical behavior.

NOTICE assumes complete responsibility for adhering to all requirements outlined in regulations and standards within the designated areas of operation and carries out the necessary activities accordingly.

NOTICE is committed to addressing reported concerns regarding impartiality and conflict of interest or unethical behavior promptly, fairly, and confidentially.

NOTICE top management and conformity assessment personnel commit that;

- They are not in close relationship (kinship, friendship etc.) which will jeopardize the impartiality with the client in question;
- They are not the designer, manufacturer, supplier, installer, purchaser, owner or maintainer of devices which they assess, nor the authorised representative of any of those parties.
- They are not involved in the design, manufacture or construction, marketing, installation and use, or maintenance of the devices for which they are designated, nor represent the parties engaged in those activities;
- They are not engaged in any activity that may conflict with their independence of judgement or integrity in relation to conformity assessment activities for which they are designated;
- They do not offer or provide any service which may jeopardise the confidence in their independence, impartiality or objectivity. In particular, they do not offer or provide consultancy services to the manufacturer, its authorised representative, a supplier or a commercial competitor as regards the design, construction, marketing or maintenance of devices or processes under assessment, and being linked to any organisation which itself provides the consultancy services mentioned above
- They have not been employed by or provided consultancy services to the client in question, their authorized representative, supplier or their commercial competitor for the last 3 years.
- They do not solicit or accept money, gifts, nor they enter into commercial or any other form of benefit making relation with clients.

NOTICE ensures the confidentiality of all information, encompassing technical, commercial, and proprietary rights, provided by the client or acquired during site audits throughout the entirety of the conformity assessment process. This includes safeguarding information such as documents, personal data, and commercial confidential information, along with trade secrets and intellectual property rights.

Employees of NOTICE bear personal responsibility for the security and confidentiality of the information they access. Through the signing of impartiality and confidentiality agreements, NOTICE commits to upholding the confidentiality of information obtained by both internal and external personnel. Adherence to confidentiality principles is mandatory for all employees, and accountability persists even after the completion of their work.

NOTICE and its personnel maintain the confidentiality of verbal or written information acquired from relevant companies and parties related to conformity assessment activities. Such information is only disclosed to Slovenska Akreditacija (SA), JAZMP, and the European Commission upon their request. Any sharing with other parties is contingent upon a court ruling in favour of disclosure, with the associated customer being duly notified. NOTICE prioritizes the utmost care in maintaining the confidentiality of customer data.

By signing service agreements and impartiality & confidentiality agreements with personnel, as well as having a top management impartiality agreement in place, the aforementioned items are ensured.

NOTICE does not audit or certify another notified body's quality system.

NOTICE does not perform internal audits and client-specific trainings for companies for which it provides conformity assessment services.

NOTICE does not provide consultancy and pre-certification services (pre-review, gap analysis, etc) nor does offer any activities which includes providing solutions to the client. All the trainings provided by NOTICE will be open-to-the-public general trainings.

NOTICE does not subcontract any part of certification activities.

NOTICE specifies the fees for services to be rendered in accordance with established processes. NOTICE ensures that it does not engage in price discrimination against their customers. NOTICE delivers services in line with established procedures that adhere to applicable rules and regulations. NOTICE does not offer a simplified or expedited process.

NOTICE will regularly review and assess their practices, policies, and procedures to identify areas for improvement and take appropriate actions to enhance impartiality within the organization.

Contact Information

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